Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation of the Effect of Mobile-Based Self-Care Training on Fatigue, Symptom Burden, and Self-Management in Hemodialysis Patients

Protocol summary

Study aim
Determining the Effect of Mobile-Based Self-Care Education on Fatigue, Symptom Burden, and Self-Management in Patients Undergoing Hemodialysis

Design
A randomized controlled clinical trial with parallel groups, single-blind

Settings and conduct
Location: Imam Reza 24-Hour Clinic, Shiraz. The data collector and the statistician will be blinded to group assignments.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Minimum literacy skills sufficient to understand the educational content Ability to understand and speak Persian Definitive diagnosis of chronic kidney disease by a nephrologist Age 18 years or older At least 6 months since the initiation of hemodialysis Undergoing hemodialysis three times per week Active access to a smartphone and the Internet, with the ability to use social media Not participating concurrently in other hemodialysis-related educational programs Exclusion Criteria: Presence of a chronic psychiatric disorder diagnosed by a physician Acute myocardial infarction and being on mechanical ventilation at the time of the study Undergoing kidney transplantation Lack of willingness to continue participation in the study Failure to attend three consecutive sessions of the provided educational content

Intervention groups
The intervention in the experimental group will consist of mobile-based self-care education. This education is structured according to the Self-Care Matrix theory across four main domains: activities, behaviors, context, and environment. In the first session, instructions on how to participate in the program will be provided through audio messages and video clips shared in the selected social media group. Control Group: Participants in this group will not receive any of the interventions provided to the experimental group.

Main outcome variables
Fatigue, Symptom Burden, and Self-Management

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251109067926N1**
Registration date: **2025-12-30, 1404/10/09**
Registration timing: **prospective**

Last update: **2025-12-30, 1404/10/09**
Update count: **0**

Registration date
2025-12-30, 1404/10/09

Registrant information

Name
Mohammad Hadi Ayati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3647 4254

Email address
mohammadh.ayt@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-21, 1404/11/01

Expected recruitment end date
2026-05-22, 1405/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the Effect of Mobile-Based Self-Care Training on Fatigue, Symptom Burden, and Self-Management in Hemodialysis Patients

Public title
Effect of Mobile-Based Self-Care Training in Hemodialysis Patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Being 18 years of age or older Having completed at least 6 months since the initiation of hemodialysis Able to understand and speak the Persian language Having active access to a smartphone and the Internet, and the ability to use social media Undergoing hemodialysis three times per week Being at least basic literacy (reading and writing skills) to understand the educational content A definitive diagnosis of chronic kidney disease confirmed by a nephrologist Not participating concurrently in other hemodialysis-related educational programs

Exclusion criteria:
Undergoing kidney transplantation Failure to view three consecutive sessions of the provided educational content Having an acute myocardial infarction and being on mechanical ventilation at the time of the study Lack of willingness on the part of the patient to continue cooperating with the researcher during the study Presence of a chronic psychiatric disorder diagnosed by a physician Hospitalization of the patient

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be enrolled in the study based on a random number table. They will then be assigned to the intervention and control groups using permuted random blocks of size four. The list of random blocks will be generated by a statistician using specialized software, and the finalized block list will be placed in sealed, numbered envelopes by the statistician. This procedure ensures an equal number of participants in both groups. After selecting each patient for allocation, the envelopes will be opened sequentially, and participants will be assigned to either the intervention or control group based on the content of the envelope. This process will continue until all envelopes have been opened and the study is completed.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, blinding will be conducted such that the research assistant responsible for data collection and the statistician performing data analysis will remain blinded to the group assignments until the end of the study.

Placebo
Not used

Assignment
Parallel

Other design features
A randomized controlled clinical trial with parallel groups, single-blind

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of the Schools of Nursing and Midwifery, Medical Management and Informatio

Street address
Zand Street, next to the Red Crescent, Central Building of Shiraz University of Medical Sciences, 7th Floor, Research Deputy Office

City
Shiraz

Province
Fars

Postal code
71348-14336

Approval date
2025-11-15, 1404/08/24

Ethics committee reference number
IR.SUMS.NUMIMG.REC.1404.097

Health conditions studied

1

Description of health condition studied
End stage Chronic kidney disease

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Fatigue
Timepoint
Before the intervention and 30 days after its initiation (after the completion of the intervention)
Method of measurement
Post dialysis fatigue scale (PDFs)

2

Description
Symptom Burden
Timepoint
Before the intervention and 30 days after its initiation (after the completion of the intervention)
Method of measurement
Dialysis Symptom Index (DSI)

3

Description
Self-Management
Timepoint
Before the intervention and 30 days after its initiation (after the completion of the intervention)
Method of measurement
Hemodialysis self-management instrument(HD-SMI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention Group: In the experimental group, the intervention will consist of mobile-based self-care education. This program is structured according to the Self-Care Matrix theory across four main domains: activities, behaviors, context, and environment.Session 1: Participants will receive instructions on how to engage with the program through audio messages and video clips shared in the selected social media group.Sessions 2–5: Focusing on the context and environment domains of the Matrix theory, education will cover the importance of social support, group communication, and support from family, friends, peers, and individuals with similar conditions, as well as support from the healthcare team, including nurses, for patients undergoing hemodialysis. Guidance will also be provided on collaborating with and participating in care alongside the family and healthcare team. Additionally, the role of self-care in hemodialysis patients will be demonstrated through short educational videos.Session 6: A brief introduction to kidney anatomy and physiology will be provided to enhance understanding of the subsequent educational content.Sessions 7–28: Based on the behavior and activity domains of the Matrix theory, content will include understanding kidney failure and its symptoms, familiarity with hemodialysis and its treatment approach, recognition of complications and symptoms related to hemodialysis, the importance of medication adherence, dietary management, and fistula care. Education on stress and anxiety management, including effective relaxation techniques, will also be provided.Final Sessions: The last two sessions will focus on spiritual communication to promote calmness and positive thinking, including strategies such as prayer, seeking intercession from the Ahl al-Bayt, and guidance on religious beliefs with encouragement for positive thinking.The self-care education will be delivered daily for one month through one of the social media platforms accepted by all participants, in the form of short video clips provided as dedicated links via the PorsLine platform. The intervention will be presented using MP4 files in a micro-teaching format. Audio narration and editing of the content will be done using Camtasia software. The final MP4 files (video and audio) will first be uploaded to the PorsLine website to ensure participants view the short videos, and then access links for each session will be shared in the selected social media group according to the scheduled program.
Category
Rehabilitation

2

Description
Control group: Control Group: Participants in the control group will receive the standard care provided at the hemodialysis center. This care includes connection to the dialysis machine and routine nursing care, such as machine adjustments, blood pressure monitoring, and other standard procedures conducted during regular hemodialysis sessions. After the completion of the study, the educational content provided to the experimental group will be shared with the control group as short daily video clips.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza 24-Hour Clinic, Shiraz
Full name of responsible person
Masoume Rambod
Street address
Shiraz, Zand Street, Namazi Square, School of Nursing and Midwifery
City
Shiraz
Province
Fars
Postal code
7193613119
Phone
+98 71 3647 4258

Email
rambodma@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Mohammadi
Street address
Shiraz, Zand Street, next to the Red Crescent, Central Building of Shiraz University of Medical Sciences, 7th Floor
City
Shiraz
Province
Fars
Postal code
7193613119
Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Masoume Rambod
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Shiraz, Zand Street, Namazi Square, School of Nursing and Midwifery, Shiraz
City
Shiraz
Province
Fars
Postal code
71936–13119
Phone
+98 71 3677 4254
Email
rambodma@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Masoume Rambod
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Shiraz, Zand Street, Namazi Square, School of Nursing and Midwifery, Shiraz
City
Shiraz
Province
Fars
Postal code
7193613119
Phone
+98 71 3647 4258
Email
rambodma@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Masoume Rambod
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Shiraz, Zand Street, Namazi Square, School of Nursing and Midwifery, Shiraz
City
Shiraz
Province
Fars
Postal code
7193613119
Phone

+98 71 3647 4258

Email

rambodma@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The primary outcomes of the study are shareable.

When the data will become available and for how long

The access period begins 6 months after publication of the article.

To whom data/document is available

Individuals and researchers at academic institutions

Under which criteria data/document could be used

The information is provided for informational purposes only.

From where data/document is obtainable

The data are accessible via email at rambodma@gmail.com

What processes are involved for a request to access data/document

The data are accessible via email at rambodma@gmail.com

Comments